

REMARKS

Initially, the Applicants would respectfully submit that the Examiner's statement as to the purportedly applicable law on the treatment of claim preambles is erroneous. Inasmuch as each of the above rejections is based upon this erroneous interpretation of law, each of the presently pending claims is allowable.

I. Summary of Official Action.

Initially, the Examiner noted that Claims 13-19 and 43-54 had been elected for examination herein, with traversal. Additionally, Claims 55-72 had been withdrawn from other consideration herein pursuant to 37 C.F.R. 1.142(b), with traversal to the restriction requirement having been made in the reply filed on August 2, 2007.

On the art, the Examiner had rejected each of Claims 13-14 for anticipation under 35 U.S.C. § 102(b) over U.S. Patent No. 6,221,176 B1 to Merchant et al., and with the following comments:

“Regarding claims 13-14, the treatment solution of Merchant contains the same pH buffering solution and the sodium nitrate as claimed. Therefore, the treatment solution of Merchant anticipates instant claims 13-14. In addition, the preamble “for forming an amorphous oxide layer over an implantable device” merely states the intended use for the claimed passivation solution, therefore, does not lend patentable weight to the instantly claimed passivation solution. Furthermore, since the treatment solution of Merchant contains the same components, one of ordinary skill in the art would also find it capable of forming an amorphous oxide layer over an implantable device as claimed.”

Yet additionally, the Examiner had rejected claims 13-17 and 43-54 under 35 U.S.C. § 103(a) as being purportedly obvious over the teachings of U.S. Patent No. 5,938,976 to Heimann et al., and with the following further comments:

“Heimann teaches a metal surface treatment solution to form a corrosion resistant coating containing an amorphous phase (abstract), wherein the treatment solution comprises precursors such as compounds having cations of Group I metals anions

such as nitrate and carbonates (col. 3 lines 7-15). Heimann's treatment solution further comprises pH buffers such as sodium hydroxide and sodium hydrogen carbonate (i.e., sodium bicarbonate)(col. 4 lines 32-46, Tables A-B).

Regarding claims 13-14, even though Hemimann does not explicitly teach the claimed sodium nitrate in the coating solution, one of the ordinary skill in the art would have found the addition of the claimed sodium nitrate in the coating solution of Heimann obvious and with expected success since Heimann teaches that suitable cations for the its precursor are Group I metals, which include sodium, and anion such as nitrate. Therefore, the precursors in the coating solution of Heimann encompass the claimed sodium nitrate. In addition, the preamble "for forming an amorphous oxide layer over an implantable device" merely states the intended use for the claimed passivation solution, therefore, does not lend patentable weight to the instantly claimed passivation solution.

Regarding claim 48, Heimann further teaches that sodium carbonate can also be used in the treatment solution (col. 7 lines 60-63, example 8) and the pH of the passivation solution is 8-12 for ion based alloys (col. 7 lines 51-54). Therefore, the pH of the treatment solution as taught by Heimann overlaps the claimed pH as recited in claim 48. A prima facie case of obviousness exists. See MPEP 2144.05. The selection of claimed pH range from the disclosed range of Heimann would have been obvious to one skilled in the art since Heimann teaches the same utilities in its' disclosed pH range.

Regarding claim 49, the recited limitation is directed to how the claimed passivation solution is being used and does not impart any specific compositional, structural or material limitation to the instantly claimed passivation solution. Therefore, the process limitation as recited in claim 49 does not render the instant claim patentable.

Regarding claims 15-17, 43-47 and 50-54, Heimann further teaches that the precursor (i.e. sodium nitrate and sodium carbonate) is present in an amount of about 1 to about 60wt% and the pH buffer additives (i.e. sodium bicarbonate and sodium hydroxide) is present in an amount of about 1 to about 60wt% (col.4 lines 25-41). Therefore, the amount of sodium nitrate, sodium carbonate, sodium bicarbonate and sodium hydroxide as taught by Heimann overlap the claimed sodium nitrate, sodium carbonate, sodium bicarbonate and sodium hydroxide concentrations. In addition, the ratio calculated from the concentrations of sodium bicarbonate, sodium carbonate and sodium hydroxide in the treatment solution of Heimann would have overlapped the claimed ratio of sodium bicarbonate, sodium carbonate and sodium hydroxide. Therefore, a prima facie case of obviousness exists. See MPEP 2144.05. The selection of claimed individual component concentration ranges and the ratio range from the disclosed ranges of Heimann would have been obvious to one skilled in the art since Heimann teaches the same utilities in its disclosed sodium nitrate, sodium carbonate, sodium biocarbonate and sodium hydroxide concentration ranges.

Yet additionally, the Examiner rejected Claims 18-19 under 35 U.S.C. § 103(a) being purportedly obvious over the proposed combination of Heimann and further in view of Sako et al. U.S. 2003/0213533 A1, and with the following comments:

The teachings of Heimann are discussed in paragraph 6 above. However, Heimann does not teach the presence of nitric acid and hydrochloric acid in the treatment solution.

Sako also teaches a metal treatment composition for corrosion inhibition (abstract). Sako further teaches that nitric acid, hydrochloric acid and sodium hydroxide can be added to the treatment solution for the purpose of adjusting pH (paragraph [0059]).

Regarding claims 18-19, one of the ordinary skill in the art would have found it obvious to use a combination of nitric acid, hydrochloric acid and sodium hydroxide as taught by Sako in the coating solution of Heimann with expected success since Sako teaches nitric acid, hydrochloric acid and sodium hydroxide are all used in a coating solution for the purpose of pH control. See MPEP 2144.06.

The above rejections are respectfully traversed, and a favorable reconsideration is respectfully solicited in view of the following further remarks.

II. The Applicable Law.

Fortunately, the Manual of Patent Examining Procedure provides helpful guidance in regards to the subject of how preambles are to be considered in the examination of patent claims. In that regard, the MPEP states, as follows:

2111.02 Effect of Preamble [R-3]

The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim. *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002). See *id.* at 808-10, 62 USPQ2d at 1784-86 for a discussion of guideposts that have emerged from various decisions exploring the preamble's effect on claim scope, as well as a hypothetical example illustrating these principles.

"[A] claim preamble has the import that the claim as a whole suggests for it." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003)(In considering the effect of the preamble in a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the claims' recitation of a patient or a human "in need" gives life and meaning to the preamble's statement of purpose.). *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) (A preamble reciting "An abrasive article" was deemed essential to point out the invention defined by claims to an article comprising abrasive grains and a hardened binder and the process of making it. The court stated "it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable inter alia of use as abrasive grains and a binder is not an 'abrasive article.'" Therefore, the preamble served to further define the structure of the article produced.).

I. PREAMBLE STATEMENTS LIMITING STRUCTURE

Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim."); *Pac-Tec Inc. v. Amerace Corp.*, 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention). See also *In re Stencel*, 828 F.2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987). (The claim at issue was directed to a driver for setting a joint of a threaded collar*>;< however>,< the body of the claim did not directly include the structure of the collar as part of the claimed article. The examiner did not consider the preamble, which did set forth the structure of the collar, as limiting the claim. The court found that the collar structure could not be ignored. While the claim was not directly limited to the collar, the collar structure recited in the preamble did limit the structure of the driver. "[T]he framework - the teachings of the prior art - against which patentability is measured is not

all drivers broadly, but drivers suitable for use in combination with this collar, for the claims are so limited." *Id.* at 1073, 828 F.2d at 754.).

II. PREAMBLE STATEMENTS RECITING PURPOSE OR INTENDED USE

The claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works*, 868 F.2d at 1257, 9 USPQ2d at 1966. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ2d at 480-81 (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim); *STX LLC. v. Brine*, 211 F.3d 588, 591, 54 USPQ2d 1347, 1350 (Fed. Cir. 2000) (holding that the preamble phrase "which provides improved playing and handling characteristics" in a claim drawn to a head for a lacrosse stick was not a claim limitation). Compare *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333-34, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003) (In a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the preamble is not merely a statement of effect that may or may not be desired or appreciated, but rather is a statement of the intentional purpose for which the method must be performed. Thus the claim is properly interpreted to mean that the vitamin preparation must be administered to a human with a recognized need to treat or prevent pernicious anemia.); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002) (A claim at issue was directed to a method of preparing a food rich in glucosinolates wherein cruciferous sprouts are harvested prior to the 2-leaf stage. The court held that the preamble phrase "rich in glucosinolates" helps define the claimed invention, as evidenced by the specification and prosecution history, and thus is a limitation of the claim (although the claim was anticipated by prior art that produced sprouts inherently "rich in glucosinolates"))).

During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963) (The claims were directed to a core member for hair curlers and a process of making a core member for hair curlers. Court held that the intended use of hair curling was of no significance to the structure and process of making.); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim did not distinguish over the prior art apparatus). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (anticipation rejection affirmed based on Board's factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant's claim 1 (a dispensing top for dispensing popcorn in a specified manner)) and cases cited therein. See also MPEP § 2112 - § 2112.02.

However, a "preamble may provide context for claim construction, particularly, where ... that preamble's statement of intended use forms the basis for distinguishing the prior art in the patent's prosecution history." *Metabolite Labs., Inc. v. Corp. of Am. Holdings*, 370 F.3d 1354, 1358-62, 71 USPQ2d 1081, 1084-87 (Fed. Cir. 2004). The patent claim at issue was directed to a two-step method for detecting a deficiency of vitamin B12 or folic acid, involving (i) assaying a body fluid for an "elevated level" of homocysteine, and (ii) "correlating" an "elevated" level with a vitamin deficiency. 370 F.3d at 1358-59, 71 USPQ2d at 1084. The court stated that the disputed claim term "correlating" can include comparing with either an unelevated level or elevated level, as opposed to only an elevated level because adding the "correlating" step in the claim during prosecution to overcome prior art tied the preamble directly to the "correlating" step. 370 F.3d at 1362, 71 USPQ2d at 1087. The recitation of the intended use of "detecting" a vitamin deficiency in the preamble rendered the claimed invention a method for "detecting," and, thus, was not limited to detecting "elevated" levels. *Id.*

See also *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d at 808-09, 62 USPQ2d at 1785 ("[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention...Without such reliance, however, a preamble generally is not limiting when the claim body

describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention." Consequently, "preamble language merely extolling benefits or features of the claimed invention does not limit the claim scope without clear reliance on those benefits or features as patentably significant."). In *Poly-America LP v. GSE Lining Tech. Inc.*, 383 F.3d 1303, 1310, 72 USPQ2d 1685, 1689 (Fed. Cir. 2004), the court stated that "a '[r]eview of the entirety of the '047 patent reveals that the preamble language relating to 'blown-film' does not state a purpose or an intended use of the invention, but rather discloses a fundamental characteristic of the claimed invention that is properly construed as a limitation of the claim..." Compare *Intirtool, Ltd. v. Texar Corp.*, 369 F.3d 1289, 1294-96, 70 USPQ2d 1780, 1783-84 (Fed. Cir. 2004) (holding that the preamble of a patent claim directed to a "hand-held punch pliers for simultaneously punching and connecting overlapping sheet metal" was not a limitation of the claim because (i) the body of the claim described a "structurally complete invention" without the preamble, and (ii) statements in prosecution history referring to "punching and connecting" function of invention did not constitute "clear reliance" on the preamble needed to make the preamble a limitation).

III. The Standards of the Prevailing Law Require Allowance.

A. The Pending Independent Claims.

The presently pending independent claims are, as follows (emphasis added, *infra*):

13. (Previously Presented) A passivation solution for forming an amorphous oxide layer over **an implantable device**, said passivation solution comprising:

a pH buffering solution; and,

sodium nitrate, wherein said sodium nitrate provides oxygen in the formation of said amorphous oxide layer over **the implantable device**.

48. (Previously Presented) A passivation solution for forming an amorphous oxide layer over **an implantable device**, said passivation solution comprising:

sodium bicarbonate;

sodium carbonate;
sodium hydroxide; and,
sodium nitrate, wherein said sodium nitrate provides oxygen in the formation of
said amorphous oxide layer over **the implantable device**, and
wherein said passivation solution comprises a pH of approximately 10 or higher.

B. Application of the Law to the Facts.

Significantly, in each of the pending claims, the preamble is specifically “tied to” an element expressly set forth in the body of the patent claim. In particular, the “implantable device” of the preamble serves as an antecedent basis for the “implantable device” set forth in an element of the main body of the patent claim.

Hence, and under the presently pending claims, it becomes manifestly clear that the preamble does indeed give life and “meaning and vitality” to the claim. *Pitney Bowes, Inc. v. Hewlett Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). *Also see, Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003). Moreover, the leading case of *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951), is directly in point.

Yet further and as the MPEP directly points out: “Any terminology in the preamble that limits the structure of the claim invention must be treated as a claim limitation. *See, Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989), as well as a plurality of other cases.

Yet further, and perhaps most importantly, the claim preamble must be in the context of the entire claim. In that regard, the elements of the claim and the main body

expressly refer to and encompass the “implantable device”. Under these circumstances, it cannot be gainsaid that somehow the “implantable device” is not an element of the claim. It is.

Yet additionally, reliance by the Applicants during prosecution in order to distinguish the claimed invention from the prior art does indeed transform the preamble into a claim limitation “because such reliance indicates the use of the preamble to define, impart, the claimed invention.” See *Catalina Mktg. Int’l v. Coolsavings.com, Inc.*, 289 F.3d at 808-09, 62 USPQ2d at 1785.

Indeed, the above case law is directly applicable herein. In independent claim 13, for example, the “sodium nitrate” is not merely an element of a solution in a bottle, or in a sprayer, dipper or other application device, but rather is an integral part of “said amorphous oxide layer of the implantable device.” Wherefore, it becomes clear that not only does the preamble refer to “an implantable device”, but also the body of the claim elements *per se* does indeed refer to the “implantable device”.

Pursuant to the above context, each of the presently pending items of prior art forming the basis of rejection herein has been reviewed. Specifically, the Merchant, Heimann and Sako references have been reviewed for **any teaching** on the subject of “implantable device”. No such teaching has been found.

In fact, these references refer to the coating of various items that are intended for use outside the human body. For example, Sako talks about articles “that are used for automobile bodies, construction materials, household electrical appliances and the like.” (See, Sako, paragraph 0001).

The Merchant reference states: "In particular, the present invention relates to treating the copper layer of a flexible circuit to prevent, minimize, and/or delay the propagation of microcracks in the copper foil layer of a flexible circuit." (Merchant, Col. 1, lines 8-13).

Finally, Heimann teaches: "It [corrosion] also causes premature replacement of equipment and parts in industrial facilities, boats and other marine vehicles, automobiles, and aircraft, among a wide range of metallic components." (Heimann, Col. 1, lines 36-39 (explanation added)).

Accordingly, the cited prior art does not teach the limitations of the presently pending patent claims, as properly understood based upon the requirements of the prevailing law.

CONCLUSION

Based upon the above statements of the prevailing law, and analysis thereof, and application of said law to the presently pending claims, it is respectfully submitted that each of the presently pending claims is allowable over the prior art of the record, and an thus early Notice of Allowance is respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "R M Ward", written over a horizontal line.

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